

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following Reference Items 1-69 (**Exhibits 1-38**) which are listed again on the accompanying Form PTO 1449 (**Exhibit A**). Applicants request that the Examiner review the publications and make them of record in the subject application.

Pursuant to the Notice appearing in the August 5, 2003 Official Gazette, because this application was filed after June 30, 2003, copies of the U.S. Patents and U.S. Patent Application Publications listed herein are not provided.

1. U.S. Patent No. 4,129,666 issued December 12, 1978 (Wizerkaniuk);
2. U.S. Patent No. 4,594,409 issued June 10, 1986 (Hayashi et al.);
3. U.S. Patent No. 5,965,600, issued October 12, 1999 (Sato et al.);
4. U.S. Patent No. 6,024,981, issued February 15, 2000 (Khankari et al);
5. U.S. Patent No. 6,162,800, issued December 19, 2000 (Dolle et al.);
6. U.S. Patent No. 6,514,938 B1, issued February 4, 2003 (Gad et al.);

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7. U.S. Patent No. 6,620,847, issued September 16, 2003
(Konfino et al.);
8. U.S. Patent No. 6,800,285 B2, issued October 5, 2004
(Rodriguez, et al.);
9. U.S. Patent No. 6,800,287 B2, issued October 5, 2004
(Gad et al.);
10. U.S. Patent No. 6,844,314 B2, issued January 18, 2005
(Eisenbach-Schwartz et al.);
11. U.S. Patent No. 6,939,539 B2, issued September 6, 2005
(Konfino et al.);
12. U.S. Patent No. 7,022,663, issued April 4, 2006
(Gilbert et al.);
13. U.S. Patent No. 7,033,582, issued April 25, 2006 (Yong,
et al.);
14. U.S. Patent No. 7,074,580, issued July 22, 2006 (Gad et
al.);
15. U.S. Patent Application Publication No. US-2002-
0037848-A1, published March 28, 2002 (Eisenbach-
Schwartz et al.);
16. U.S. Patent Publication No. US-2002-0115103-A1,
published August 22, 2002 (Gad et al.);

17. U.S. Patent Publication No. US-2002-0107388-A1,
published August 8, 2002 (Vandenbark);
18. U.S. Patent Application Publication US-2002-0077278,
published June 20, 2002 (Yong et al.);
19. U.S. Patent Publication No. US-2003-0170729-A1,
published September 11, 2003 (Klinger);
20. U.S. Patent Publication No. US-2004-0006022-A1,
published January 8, 2004 (Strominger et al.);
21. U.S. Patent Publication No. US-2004-0106554 A1,
published June 3, 2004 (Konfino et al.);
22. U.S. Patent Publication No. US-2005-0014694 A1,
published January 20, 2005 (Yong et al.);
23. U.S. Patent Publication No. US-2005-0019322 A1,
published January 27, 2005 (Rodriguez, et al.);
24. U.S. Patent Publication No. US-2005-0038233 A1,
published February 17, 2005 (Gad et al.);
25. U.S. Patent Publication No. US-2005-0170004 A1,
published August 4, 2005 (Rosenberger et al.);
26. U.S. Patent Publication No. US-2005-0171286 A1,
published August 4, 2005 (Konfino et al.);
27. U.S. Patent Publication No. US-2005-0256046 A1,
published November 17, 2005 (Gad et al.);

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28. U.S. Patent Application Publication No. US-2006-0052586, published March 9, 2006 (Dolitzky);
29. U.S. Patent Application Publication No. US-2006-0122113, published June 8, 2006 (Pinchasi et al.);
30. U.S. Serial No. 09/885,227, filed June 20, 2001 (Rodriguez and Ure); (**Exhibit 1**)
31. U.S. Serial No. 10/547,463, filed August 30, 2005 (Pinchasi et al.); (**Exhibit 2**)
32. U.S. Serial No. 10/556,454, filed November 17, 2005 (Vollmer); (**Exhibit 3**)
33. U.S. Serial No. 10/577,588, filed April 27, 2006 (Rosenberger et al.); (**Exhibit 4**)
34. U.S. Serial No. 11/228,850, filed September 14, 2005 (Schwartz et al.); (**Exhibit 5**)
35. U.S. Serial No. 11/336,251, filed January 20, 2006 (Dolitzky); (**Exhibit 6**)
36. U.S. Serial No. 11/373,794, filed March 9, 2006 (Pinchasi); (**Exhibit 7**)
37. European Patent No. EP 0 378 246 A1, published June 18, 1986 (Hunter) (**Exhibit 8**);
38. German Patent No. DE 3 930 733, issued March 28, 1991 (Vincze et al.) English-language abstract also being

submitted. Applicants point out that this reference is a counterpart of European Patent No. 0 417 588, which is also being submitted and contains English-language claims. **(Exhibit 9);**

39. New Zealand Patent No. 254496, issued August 27, 1996 (McLean et al.) Applicants point out that this reference is a counterpart of PCT International Publication No. WO 94/03484 (PCT/US93/06249) which is being submitted. The New Zealand Patent Bibliographic Data Sheet is also being submitted. **(Exhibit 10);**

40. New Zealand Patent No. 336690, issued January 12, 1998 (Arnon et al.) Applicants point out that this reference is a counterpart of U.S. Patent No. 6,214,791;

41. Russian Patent No. SU1690368, issued August 20, 1995 (Vlasov et al.) English-language abstract also being submitted **(Exhibit 11);**

42. Russian Patent No. SU1469826, issued November 20, 1995 (Vlasov et al.) English-language abstract also being submitted **(Exhibit 12);**

43. South African Patent No. 98/0214, issued September 29, 1999 (Arnon et al.). Applicants point out that this reference corresponds to U.S. Patent No. 6,214,791;

44. Soviet Union Patent No. SU1182051, issued September 30, 1985 (Khalikov et al.) English-language abstract also being submitted **(Exhibit 13);**

45. Soviet Union Patent No. SU1664845, issued July 23, 1991 (Korn et al.) English-language abstract also being submitted (**Exhibit 14**);
46. PCT International Publication No. WO 03/048735 (PCT/US02/38859), published June 12, 2003 (Klinger) (**Exhibit 15**);
47. PCT International Publication No. WO 06/050122 (PCT/US05/039003), published May 11, 2006 (Ray et al.) (**Exhibit 16**);
48. Aharoni, et al., "Copolymer 1 induces T cells of the T helper type 2 that crossreact with myelin basic protein and suppress experimental autoimmune encephalomyelitis", Proc. Natl. Acad. Sci. USA, 1997, 94, 10821-10826 (**Exhibit 17**);
49. Aharoni, et al., "Cop 1 Specific Suppressor Cells Inhibit Experimental Allergic Encephalomyelitis Induced by Either Mouse Spinal Cord Homogenate or Proteolipid Protein Peptide 139-151", Neurology, 1997, Vol. 48, No. 3, A422 (Abstract) (**Exhibit 18**);
50. Aharoni, et al., "Bystander Suppression of Experimental Autoimmune Encephalomyelitis by T Cell Lines and Clones of the Th2 Type Induced by Copolymer 1", J. Neuroimmunol. 1998, 91(1-2), 135-146 (**Exhibit 19**);
51. Bodanszky, M., "Principles of Peptide Synthesis", Springer-Verlag, Berlin, Heidelberg, New York, Tokyo, 1984, pp. 118-229 (**Exhibit 20**);

52. Bornstein, et al., "Rationale For Immunomodulating Therapies of Multiple Sclerosis: Clinical Trial Design In Multiple Sclerosis Therapy", Neurol., 1988, Vol. 38 (Suppl.2), pp. 80-81 (**Exhibit 21**);
53. Bornstein, M., "Clinical Experience: Hopeful Prospects In Multiple Sclerosis", Hospital Practice, 1992, Vol. 27, No. 5, pp. 135-158 (**Exhibit 22**);
54. Cazzato, et al., "Treatment of Multiple Sclerosis. The Present and the Future. Study Group on Diagnosis and Therapy of Multiple Sclerosis", Database Medline on STN, Instituto do Clinica Neurologica, Universit'a, Trieste, Italy: Medline AN: 2000060325, Recent Progressi in Medicina. October 1999, 90(10), 538-544 (**Exhibit 23**);
55. Duda, et al., "Human and Murine CD4 T Cell Reactivity to a Complex Antigen: Recognition of the Synthetic Random Polypeptide Glatiramer Acetate", The Journal of Immunology, 2000, 165, 7300-7307 (**Exhibit 24**);
56. Gurevich, "Study of the MHC-competition Between BP and Cop 1 Using Human Cytotoxic T-cell Clones", Israel J. Med. Sci., 1993 (Abstract) (**Exhibit 25**);
57. Johnson, et al. "Copolymer 1 reduces relapse rate and improves disability in relapsing-remitting multiple sclerosis: results of a phase III multicenter, double-blind placebo-controlled trial. The Copolymer 1

Multiple Sclerosis Study Group", Neurology, 45(7), 1268
(Abstract) (**Exhibit 26**);

58. Korczyn, et al., "Safety profile of copolymer 1:
analysis of cumulative experience in the United States
and Israel", J. Neurol, 1996, Vol. 243 (Suppl. 1): S23-
S26 (**Exhibit 27**);

59. Lovell, K. and Jones, M., "CNS Infections, Spongiform
Encephalopathy and Demyelinating Diseases", Karol
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updated on 2003-04-20,
<URL:http://ampat.amu.edu.pl/guzyuno/CNS_INFE.HTM>
(**Exhibit 28**);

60. Merck Manual of Diagnosis and Therapy, Merck Research
Laboratories, Whitehouse Section, N.J., 17th Ed.,
1999, pp. 1300-1303, pp. 1312-1317 (**Exhibit 29**);

61. Pharmacia Biotech Directory, 1996, pp. 340-341 (**Exhibit
30**);

62. Physician's Desk Reference, 2000, Medical Economics Co.
Inc., Montvale, NJ, 3115 (**Exhibit 31**);

63. Rothbard, et al., "Interactions Between Immunogenic
Peptides and MHC Proteins", Annu. Rev. Immunol., 1991,
9, 527-565 (**Exhibit 32**);

64. Salvetti, et al., "Myelin Basic Protein T Cell Epitopes
in Patients with Multiple Sclerosis", Department of

Neurological Sciences, University of Rome, La Sapienza
1991, 72 (Abstract) (**Exhibit 33**);

65. Sela, et al., "Synthetic Approaches To Vaccines For Infectious And Autoimmune Diseases", Vaccine, 1992, Vol. 10, No. 14, pp. 991-999 (**Exhibit 34**);
66. Stark, "Expanded Clinical Trials of Treatments for Multiple Sclerosis (MS): Copolymer 1 (COP-1) Treatment Investigational New Drug (IND) Program", Ann. Neurol., 1994, 36, 114-115 (**Exhibit 35**);
67. Teva, et al., "Copolymer-1 Glatiramer Acetate Copaxone Agent for Multiple Sclerosis", Drugs of the Future, 1998, Vol. 23, No. 2, pp. 213-214 (**Exhibit 36**);
68. Webb, et al., "Suppression of Experimental Allergic Encephalomyelitis in Rhesus Monkeys by a Synthetic Basic Copolymer", Isr. J. Med. Sci., 1975, 11, 1388 (Abstract) (**Exhibit 37**); and
69. Wieseemann, et al., "Glatiramer Acetate (GA) induces IL-13/IL-5 secretion in naïve T cells", Journal of Neuroimmunology, 2001, 119, 137-144 (**Exhibit 38**).

This Supplemental Information Disclosure Statement is being submitted after the mailing of the first Office Action but before the mailing date of a final Office Action. Under C.F.R. §1.97(c) and §1.17(p), the fee for filing an Information Disclosure Statement after the mailing of the first Office Action on the merits but prior to the mailing of a final Office Action is ONE HUNDRED EIGHTY DOLLARS (\$180.00) and a check including this amount is enclosed. Accordingly,

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applicants request that this Supplemental Information Disclosure Statement be considered.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee, other than the \$1,020.00 fee for three-month extension of deadline and \$180.00 for Information Disclosure Statement, is deemed necessary in connection with the filing of this Response. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

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Form PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeAtty. Docket No.
60726-AZU.S. Serial No.
10/776,442INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)Applicant:
Moses Rodriguez and Daren UreFiling Date:
February 10, 2004Group Art Unit
1614

U.S. PATENT DOCUMENTS

| Examiner Initial | Document Number | Date | Name | Class | Subclass | Filing Date if Appropriate |
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| 2 | 4 5 9 4 4 0 9 | 6/10/86 | Hayashi et al.; | | | |
| 3 | 5 9 6 5 6 0 0 | 10/12/99 | Sato et al.; | | | |
| 4 | 6 0 2 4 9 8 1 | 2/15/00 | Khankari et al.; | | | |
| 5 | 6 1 6 2 8 0 0 | 12/19/00 | Dolle et al.; | | | |
| 6 | 6 5 1 4 9 3 8 | 2/4/03 | Gad et al.; | | | |
| 7 | 6 6 2 0 8 4 7 | 9/16/03 | Konfino et al.; | | | |
| 8 | 6 8 0 0 2 8 5 | 10/5/04 | Rodriguez et al.; | | | |
| 9 | 6 8 0 0 2 8 7 | 10/5/04 | Gad et al.; | | | |
| 10 | 6 8 4 4 3 1 4 | 1/18/05 | Eisenbach-Schwartz et al.; | | | |
| 11 | 6 9 3 9 5 3 9 | 9/6/05 | Konfino et al.; | | | |
| 12 | 7 0 2 2 6 6 3 | 4/4/06 | Gilbert et al.; | | | |

| Document Number | Date | Country | Class | Subclass | Translation |
|-----------------|---------------|---------|----------|----------|-------------|
| | | | | | Yes No |
| 37 | 0 3 7 8 2 4 6 | 6/18/86 | Europe; | | |
| 38 | 3 9 3 0 7 3 3 | 3/28/91 | Germany; | | |

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| 48 | Aharoni, et al., "Copolymer 1 induces T cells of the T helper type 2 that crossreact with myelin basic protein and suppress experimental autoimmune encephalomyelitis", <u>Proc. Natl. Acad. Sci. USA</u> , 1997, 94, 10821-10826; |
| 49 | Aharoni, et al., "Cop 1 Specific Suppressor Cells Inhibit Experimental Allergic Encephalomyelitis Induced by Either Mouse Spinal Cord Homogenate or Proteolipid Protein Peptide 139-151", <u>Neurology</u> , 1997, Vol. 48, No. 3, A422 (Abstract); |
| 50 | Aharoni, et al., "Bystander Suppression of Experimental Autoimmune Encephalomyelitis by T Cell Lines and Clones of the Th2 Type Induced by Copolymer 1", <u>J. Neuroimmunol.</u> 1998, 91(1-2), 135-146; |
| 51 | Bodanszky, M., "Principles of Peptide Synthesis", Springer-Verlag, Berlin, Heidelberg, New York, Tokyo, 1984, pp. 118-229; |
| 52 | Bornstein, et al., "Rationale For Immunomodulating Therapies of Multiple Sclerosis: Clinical Trial Design In Multiple Sclerosis Therapy", <u>Neurol.</u> , 1988, Vol. 38 (Suppl.2), pp. 80-81; |
| 53 | Bornstein, M., "Clinical Experience: Hopeful Prospects In Multiple Sclerosis", <u>Hospital Practice</u> , 1992, Vol. 27, No. 5, pp. 135-158; |
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| 55 | Duda, et al., "Human and Murine CD4 T Cell Reactivity to a Complex Antigen: Recognition of the Synthetic Random Polypeptide Glatiramer Acetate", <u>The Journal of Immunology</u> , 2000, 165, 7300-7307; |
| 56 | Gurevich, "Study of the MHC-competition Between BP and Cop 1 Using Human Cytotoxic T-cell Clones", <u>Israel J. Med. Sci.</u> , 1993 (Abstract); |
| 57 | Johnson, et al. "Copolymer 1 reduces relapse rate and improves disability in relapsing-remitting multiple sclerosis: results of a phase III multicenter, double-blind placebo-controlled trial. The Copolymer 1 Multiple Sclerosis Study Group", <u>Neurology</u> , 45(7), 1268 (Abstract); |

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Inventors: Moses Rodríguez and Dare Ure
Serial No.: 10/776,442
Filed: February 10, 2004
Exhibit A

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|----------------------------------------------------------------------|------------------------------------------------------------|---------------------------------------------|-------------------------------|
| Form PTO-1449 | U.S. Department of Commerce Patent and Trademark Office | Atty. Docket No. 60726-AZ | U.S. Serial No. 10/776,442 |
| INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) | | Applicant: Moses Rodriguez and Daren Ure | |
| | | Filing Date: February 10, 2004 | Group Art Unit 1614 |

U.S. PATENT DOCUMENTS

| Examiner Initial | | Document Number | Date | Name | Class | Subclass | Filing Date if Appropriate |
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| | 13 | 7 0 3 3 5 8 2 | 4/25/06 | Yong, et al.; | | | |
| | 14 | 7 0 7 4 5 8 0 | 7/22/06 | Gad et al.; | | | |
| | 15 | 20 02 00 37 8 4 8 | 3/28/02 | Eisenbach-Schwartz et al.; | | | |
| | 16 | 20 02 01 15 1 0 3 | 8/22/02 | Gad et al.; | | | |
| | 17 | 20 02 01 07 3 8 8 | 8/8/02 | Vandenbark; | | | |
| | 18 | 20 02 00 77 2 7 8 | 6/20/02 | Yong et al.; | | | |
| | 19 | 20 03 01 70 7 2 9 | 9/11/03 | Klinger; | | | |
| | 20 | 20 04 00 06 0 2 2 | 1/8/04 | Strominger et al.; | | | |
| | 21 | 20 04 01 06 5 5 4 | 6/3/04 | Konfino et al.; | | | |
| | 22 | 20 05 00 14 6 9 4 | 1/20/05 | Yong et al.; | | | |
| | 23 | 20 05 00 19 3 2 2 | 1/27/05 | Rodriguez et al.; | | | |
| | 24 | 20 05 00 38 2 3 3 | 2/17/05 | Gad et al.; | | | |

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| | | | | | | | Yes | No |
| | 39 | 0 2 5 4 4 9 6 | 8/27/96 | New Zealand; | | | | |
| | 40 | 0 3 3 6 6 9 0 | 1/12/98 | New Zealand; | | | | |

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| | 58 | Korczyn, et al., "Safety profile of copolymer 1: analysis of cumulative experience in the United States and Israel", <u>J. Neurol.</u> , 1996, Vol. 243 (Suppl. 1): S23-S26; |
| | 59 | Lovell, K. and Jones, M., "CNS Infections, Spongiform Encephalopathy and Demyelinating Diseases", Karol Marcinkowski U. Med. Sci., Dept. Pathol., Poland, last updated on 2003-04-20, URL: http://ampat.amu.edu.pl/guzyuno/CNS_INFE.HTM ; |
| | 60 | Merck Manual of Diagnosis and Therapy, <u>Merck Research Laboratories</u> , Whitehouse Section, N.J., 17 th Ed., 1999, pp. 1300-1303, pp. 1312-1317; |
| | 61 | Pharmacia Biotech Directory, 1996, pp. 340-341; |
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| | 63 | Rothbard, et al., "Interactions Between Immunogenic Peptides and MHC Proteins", <u>Annu. Rev. Immunol.</u> , 1991, 9, 527-565; |
| | 64 | Salvetti, et al., "Myelin Basic Protein T Cell Epitopes in Patients with Multiple Sclerosis", <u>Department of Neurological Sciences, University of Rome, La Sapienza</u> 1991, 72 (Abstract); |
| | 65 | Sela, et al., "Synthetic Approaches To Vaccines For Infectious And Autoimmune Diseases", <u>Vaccine</u> , 1992, Vol. 10, No. 14, pp. 991-999; |
| | 66 | Stark, "Expanded Clinical Trials of Treatments for Multiple Sclerosis (MS): Copolymer 1 (COP-1) Treatment Investigational New Drug (IND) Program", <u>Ann. Neurol.</u> , 1994, 36, 114-115 |

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| | 26 | 20 | 05 | 01 | 71 | 2 | 8 | 6 | 8/4/05 | Konfino et al.; | | | |
| | 27 | 20 | 05 | 02 | 56 | 0 | 4 | 6 | 11/17/05 | Gad et al.; | | | |
| | 28 | 20 | 06 | 00 | 52 | 5 | 8 | 6 | 3/9/06 | Dolitzky; | | | |
| | 29 | 20 | 06 | 01 | 22 | 1 | 1 | 3 | 6/8/06 | Pinchasi et al.; | | | |
| | 30 | 09 | 8 | 8 | 5 | 2 | 2 | 7 | 6/20/01 | Rodriguez and Ure; | | | |
| | 31 | 10 | 5 | 4 | 7 | 4 | 6 | 3 | 8/30/05 | Pinchasi et al.; | | | |
| | 32 | 10 | 5 | 5 | 6 | 4 | 5 | 4 | 11/17/05 | Vollmer; | | | |
| | 33 | 10 | 5 | 7 | 7 | 5 | 8 | 8 | 4/27/06 | Rosenberger et al.; | | | |
| | 34 | 11 | 2 | 2 | 8 | 8 | 5 | 0 | 9/14/05 | Schwartz et al.; | | | |
| | 35 | 11 | 3 | 3 | 6 | 2 | 5 | 1 | 1/20/06 | Dolitzky; | | | |
| | 36 | 11 | 3 | 7 | 3 | 7 | 9 | 4 | 3/9/06 | Pinchasi; | | | |
| FOREIGN PATENT DOCUMENTS | | | | | | | | | | | | | |
| | | Document Number | | | | Date | | | Country | Class | Subclass | Translation | |
| | | | | | | | | | | | | Yes | No |
| | 41 | 1 | 6 | 9 | 0 | 3 | 6 | 8 | 8/20/95 | Russia; | | | |
| | 42 | 1 | 4 | 6 | 9 | 8 | 2 | 6 | 11/20/95 | Russia; | | | |
| | 43 | 0 | 9 | 8 | 0 | 2 | 1 | 4 | 9/29/99 | South Africa; | | | |
| | 44 | 1 | 1 | 8 | 2 | 0 | 5 | 1 | 9/30/85 | Soviet Union; | | | |
| | 45 | 1 | 6 | 6 | 4 | 8 | 4 | 5 | 7/23/91 | Soviet Union; | | | |
| | 46 | 03 | 0 | 4 | 8 | 7 | 3 | 5 | 6/12/03 | WO; | | | |
| | 47 | 06 | 0 | 5 | 0 | 1 | 2 | 2 | 5/11/06 | WO; | | | |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | | | | | | | |
| | 67 | Teva, et al., "Copolymer-1 Glatiramer Acetate Copaxone Agent for Multiple Sclerosis", <u>Drugs of the Future</u> , 1998, Vol. 23, No. 2, pp. 213-214; | | | | | | | | | | | |
| | 68 | Webb, et al., "Suppression of Experimental Allergic Encephalomyelitis in Rhesus Monkeys by a Synthetic Basic Copolymer", <u>Isr. J. Med. Sci.</u> , 1975, <u>11</u> , 1388 (Abstract); | | | | | | | | | | | |
| | 69 | Wiesemann, et al., "Glatiramer Acetate (GA) induces IL-13/IL-5 secretion in naïve T cells", <u>Journal of Neuroimmunology</u> , 2001, 119, 137-144; | | | | | | | | | | | |
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